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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/409,800	09/30/1999	FREDERICK R. BLATTNER	960296.95939	5901

26734 7590 09/25/2002

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EXAMINER
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EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/25/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/409,800

Applicant(s)

BLATTNER ET AL.

Examiner

Juliet C Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 12 is/are rejected.
- 7) ☒ Claim(s) 10-11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. This action is written in response applicant's correspondence submitted 6/11/02, paper number 16. Claims 9 and 10 have been amended and claims 12 has been added. Applicant requested that claims 1-8 be withdrawn as non-elected. It is not clear if this request meant for the claims to be cancelled, or merely withdrawn from consideration. Thus, the claims remain pending, awaiting further clarification. Claims 1-12 are pending. Claims 1-8 are withdrawn from consideration and claims 9-12 are examined herein. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Election/Restrictions***

2. Applicant traverses the restriction of the claims to a single open reading frame. The claims have been amended and limited to a single open reading frame, thus the arguments presented are technically moot. However, the traversal is addressed nonetheless. Applicants contend "that this requirement is unduly restrictive and in appropriate," further stating that "The Examiner's restriction and requirement that applicants elect a single species is unduly restrictive, burdensome, and not in accordance with the Patent Office practice or rules which have existed to date." However, applicants do not provide any reasoning or argument to support these statements. Contrary to applicant's contentions, the restriction requirement is entirely within Patent Office practice and rules which allow for restriction to a single independent and distinct invention under 35 U.S.C. 121, as discussed in the previous office action. Thus, the restriction requirement is maintained.

*Drawings*

3. In order to avoid abandonment, the drawing informalities noted in Paper No. 14, mailed on 12/11/01, must now be corrected. A PTO 948 was mailed with that Office Action.

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

***Claim Rejections - 35 USC § 112***

4. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite over the recitation “contained in SEQ ID NO: 3, nucleotides 2389-2826” because it is not clear if this means the claim is drawn to an isolated nucleic acid comprising at least 25 contiguous nucleotides from within nucleotides 2389 to 2826 of SEQ ID NO: 3 or that the claim is drawn to an isolated nucleic acid comprising at least 25 continuous nucleotides from SEQ ID NO: 3, wherein the 25 nucleotides comprise 2389 to 2826 of SEQ ID NO: 3.

5. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claim is drawn to an isolated polynucleotide sequence comprising a DNA molecule of at least 25 contiguous nucleotides of SEQ ID NO: 3, nucleotides 2389 to 2826 or the complement to such 25 contiguous nucleotides. This genus is quite broad, encompassing any nucleic acid that has 25 nucleotides in common with nucleotides 2389-2826 of instant SEQ ID NO: 3, including variant and polymorphic sequences, as well as nucleic acids isolated from completely different organisms that may encode different polypeptides with different activities from Y004. The specification only teaches the nucleic acid comprising nucleotides 2389-2826

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of SEQ ID NO: 3. Thus, applicant has express possession of only one species in a genus which comprises many different possibilities.

As is taught by the specification, this claim encompasses versions of Y004 that are present in any possible strain of *Yersinia pestis*, including allelic variants and different possible forms of the ORF (see specification, page 11, lines 6-10).

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only one example of nucleotides 2389-2826 of SEQ ID NO: 3 are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids comprising 25 nucleotides in common with nucleotides 2389-2826 of SEQ ID NO: 3, other than SEQ ID NO: 3 itself.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Hu *et al.* (Journal of Bacteriology, Oct. 1998, p. 5192-5202).

This rejection applies to claim 9 when it is interpreted to be drawn to an isolated nucleic acid comprising nucleotides 2389-2826 of SEQ ID NO: 3. Hu *et al.* teach the entire sequence of the Y. pestis pPCP1 plasmid. Nucleotides 2389-2826 of SEQ ID NO: 3 are identical to nucleotides 3490-3927 of the sequence taught by Hu *et al.* These nucleotides are within the region designated by Hu *et al.* as the origin of replication on pPCP1.

This reference is being applied as a reference under 102(b) because it was described in a printed publication more than one year prior to applicant's filing date. The Journal of Bacteriology, Vol. 180, number 19 arrived at the National Library of Medicine on September 28, 1998 (as confirmed by a telephone call made to the library by the Examiner).

8. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by the record GenBank Accession AJ001708, version 1 (GI:2660511).

The GenBank record teaches an isolated polynucleotide sequence comprising a DNA molecule of at least 25 contiguous nucleotides of SEQ ID NO: 3, nucleotides 2389 to 2826 or the complement to such 25 contiguous nucleotides. Specifically, the GenBank record teaches a nucleic acid comprising nucleotides 2430-2509 of instant SEQ ID NO: 3 (see nucleotides 2789-2748 of the GenBank record). The nucleic acid provided in the GenBank record also comprises nucleotides 2535-2712 of instant SEQ ID NO: 3 (see nucleotides 2772-2789 of the GenBank record). Thus, the teachings in the GenBank record meet the limitations of claim 12.

*Conclusion*

9. Claims 10-11 are objected to as being dependent from a rejected base claim. If rewritten in independent form to include all of the limitations of the independent claims, these claims would be allowable. The prior art does not teach or suggest recombinant vectors or hosts transformed comprising nucleotides 2389 to 2826 of instant SEQ ID NO: 3. The closest prior art, provided by Hu et al. provides no motivation to place this particular portion of the nucleic acid they teach into a vector.

10. The instantly claimed nucleic acid, vectors and host cells have patentable utility because the nucleic acid comprising nucleotides 2389-2826 of SEQ ID NO: 3 is useful to detect *Y. pestis*. The vector and host can be used to produce additional copies of the nucleic acid comprising nucleotides 2389-2826 of SEQ ID NO: 3, and thus have utility because the nucleic acid itself has utility.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Juliet C Einsmann  
Examiner  
Art Unit 1655

September 5, 2002



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600